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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,127	06/01/2001	Anker Jon Hansen	5776.204-US	1919

7590 01/09/2003

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EXAMINER

GOLDBERG, JEROME D

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 01/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,127

Applicant(s)

HANSEN ET AL.

Examiner

Jerome D Goldberg

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 6-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5 and 34 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

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Claims 6-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention^{er}, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Applicant's elected a specific azocin ~~pyr~~^{pyr}idinecarboxylic acid compound. This election is modified in that compounds wherein $y \Rightarrow \text{N-CH}_2$, p and $q = 0$ and 1 , $x = \text{CH-CH}_2$ or $\text{CH}_2\text{-CH}_2\text{-CH}_2$ and $Z = \text{pyr}^{pyr}idinecarboxylic acid will be examined.$

The other compounds not include above will support separate patent for the reasons fully set forth in Paper No.7, page 2. Therefore, this restriction requirement is herein made final.

Claims 1-5 and 34 will be examined as they read on the elected invention as set forth above.

Claims 1,2,4,5 and 34 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific cancers disclosed, does not reasonably provide enablement for the terms "a condition related to angiogenesis" and "cancer". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The terms "a condition related to angiogenesis" in claims 1,4,5 and 34 and "cancer" in claim 2 lacks clear exemplary support in the specification as filed. The term "a condition related to angiogenesis" reads on "cancer" (see claim 2).

The cancer therapy art remains highly unpredictable, and no examples exist for efficacy of a simple compound against cancer generally. Therefore, based on the unpredictable nature of the invention and lack of guidance and working examples, and extreme breadth of the claims, one skilled in this art could not use the entire scope of the claimed invention without undue experimentation. Changing the terms to specific cancers disclosed would overcome this rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,2,4,5 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Jorgensen et al wo 96/31497 publication of record.

The wo 96/31497 was published on October 10,1996 while the instant application has an effective date December 7,1998. The wo 96/31497 publication teaches a ^{or}portion isomer of the azocin compound, 1-(3-(11,12-dihydro-6H-dibenz (d,f) azocin-s-yl)-1-propyl-3-py⁴peridinecarboxylic acid for treating a cancer patient for cancer pain (See page 6, lines 22 and 23 and page 9, line 4). The publication further teaches that compound is "suitable for oral administration"(page 12, line12) at a rate of "1-500mg/day,e.g. about 100mg per dose, when administered to patients, e.g. humans, as a drug "(page 13, lines 22-24). Therefore, one skilled in this art would find ample motivation from the prior art supra to employ the position isomer of the instant claims with a reasonable expectation that said position isomer would be effective in treating said cancer.

Claims 3 are object to as depend on a rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerome Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday-Thursday from 9am to 3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Goldberg/dl

January 7, 2003

A handwritten signature in black ink, appearing to read 'J. Goldberg', with a stylized, flowing script.

JEROME D. GOLDBERG
PRIMARY EXAMINER